(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under this part;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the reporting site submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

(d) The name of the manufacturer and the registration number submitted under paragraph (c)(1) of this section shall be the same as the reporting site that submitted the reports required by §§803.52, 803.53, and 803.55. Multireporting site manufacturers who choose to certify centrally must identify the reporting sites, by registration number and name covered by the certification, and provide the information required by paragraphs (c)(2) and (c)(3) of this section for each reporting site.

[62 FR 13306, Mar. 20, 1997]

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.57 was stayed indefinitely.

§803.58 Foreign manufacturers.

(a) Every foreign manufacturer whose devices are distributed in the United States shall designate a U.S. agent to be responsible for reporting in accordance with §807.40 of this chapter. The U.S. designated agent accepts responsibility for the duties that such designation entails. Upon the effective date of this regulation, foreign manufacturers shall inform FDA, by letter, of the name and address of the U.S. agent designated under this section and §807.40 of this chapter, and shall update this information as necessary. Such updated information shall be submitted to FDA, within 5 days of a change in the designated agent information.

(b) U.S.-designated agents of foreign manufacturers are required to:

(1) Report to FDA in accordance with §§803.50, 803.52, 803.53, 803.55, and 803.56;

(2) Conduct, or obtain from the foreign manufacturer the necessary information regarding, the investigation and evaluation of the event to comport with the requirements of §803.50;

(3) Certify in accordance with §803.57;

(4) Forward MDR complaints to the foreign manufacturer and maintain documentation of this requirement;

(5) Maintain complaint files in accordance with §803.18; and

(6) Register, list, and submit premarket notifications in accordance with part 807 of this chapter.

EFFECTIVE DATE NOTE: At 61 FR 38347, July 23, 1996, §803.58 was stayed indefinitely.

PART 804—MEDICAL DEVICE DISTRIBUTOR REPORTING

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AUTHORITY: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

SOURCE: 58 FR 46519, Sept. 1, 1993, unless otherwise noted.

Subpart A—General Provisions

§804.1 Scope.

(a) FDA is requiring medical device distributors to report deaths, serious illnesses, and serious injuries that are attributed to medical devices. Distributors are also required to report certain device malfunctions and to submit a report to FDA annually certifying the number of medical device reports filed during the preceding year, or that no reports were filed. These reports enable FDA to protect the public health by helping to ensure that devices are not adulterated or misbranded and are otherwise safe and effective for their intended use. In addition, device distributors are required to establish and maintain complaint files

or incident files as described in § 804.35, and to permit any authorized FDA employee at all reasonable times to have access to, and to copy and verify, the records contained in this file. This part supplements, and does not supersede, other provisions of this subchapter, including the provisions of part 820 of this chapter.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to chapter I of title 21, unless otherwise noted.

§ 804.3 Definitions.

(a) Act means the Federal Food, Drug, and Cosmetic Act.

(b)-(c) [Reserved]

(d) *Distributor* means any person, including any person who imports a device into the United States, who furthers the marketing of a device from the original place of manufacture to the person who makes final delivery or sale to the ultimate user but who does not repackage or otherwise change the container, wrapper, or labeling of the device or device package. One who repackages or otherwise changes the container, wrapper, or labeling, is a manufacturer under § 804.3(k).

(e) *Distributor Report Number* means the number that uniquely identifies each report submitted by a distributor. Distributors who receive or submit reports shall use their seven digit FDA registration number, calendar year that the report is received, and a sequence number. For example, the complete number will appear as follows: 1234567–1991–0001. Distributor report numbers shall also be required on FDA form 3500A.

(f) *FDA* means the Food and Drug Administration.

(g) [Reserved]

(h) *Incident files* are those files containing documents or other information, which are related to adverse events that may have been caused by a device.

(i) *Information that reasonably suggests that there is a probability that a device has caused or contributed to a death or serious injury or serious illness* means information, including professional, scientific, or medical facts, observations, or opinions, which would cause a reasonable person to believe that a device caused or contributed to a death, serious injury, or serious illness.

(j) *Malfunction* means the failure of a device to meet any of its performance specifications or otherwise to perform as intended. Performance specifications include all claims made in the labeling for the device. The intended performance of a device refers to the objective intent of the persons legally responsible for the labeling of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It also may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used to perform a function for which it is neither labeled nor advertised.

(k) *Manufacturer* means any person who manufactures, prepares, propagates, compounds, assembles, or processes a device chemically, physically, biologically, or by other procedures. The term includes any person who:

(1) Repackages or otherwise changes the container, wrapper, or labeling of a device in furtherance of the distribution of the device from the original place of manufacture, to the person who makes final delivery or sale to the ultimate user or consumer;

(2) Initiates specifications for devices that are manufactured by a second party for subsequent distribution by the person initiating the specifications; or

(3) Manufactures components or accessories which are devices that are ready to be used and are intended to be commercially distributed and are intended to be used as is, or are processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.

(l) *MDR* means medical device report.

(m) *MDR reportable event* means:

(1) The event for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that a device has caused or contributed to a death, serious illness, or serious injury; or

(2) The event for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device may have caused or contributed to a death or serious injury; or

(3) A malfunction, for which a distributor, other than an importer, required to report under this part has received or become aware of information that reasonably suggests that there is a probability that the device, if the malfunction were to recur, would be likely to cause or contribute to a death, serious illness, or serious injury; or

(4) A malfunction, for which an importer required to report under this part has received or become aware of information that reasonably suggests that a device has malfunctioned and that such device or a similar device would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(n)-(p) [Reserved]

(q) *Permanent* means nonreversible impairment or damage.

(r) *Probability, probable, or probably* means, for purposes of this section, that a person would have reason to believe, based upon an analysis of the event and device, that the device has caused or contributed to an adverse event. This term does not signify statistical probability.

(s) *A remedial action* is any recall, repair, modification, adjustment, relabeling, destruction, inspection, patient monitoring, notification, or any other action relating to a device that is initiated by a distributor, in response to information that it receives or otherwise becomes aware of, that reasonably suggests that one of its marketed devices has caused or contributed to an MDR reportable event.

(t) *Serious illness* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to the body structure; or

(3) Necessitates immediate medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(u) *Serious injury* means an event that:

(1) Is life threatening;

(2) Results in permanent impairment of a body function or permanent damage to a body structure, or

(3) Necessitates medical or surgical intervention to preclude permanent impairment of a body function or permanent damage to a body structure.

(v) [Reserved]

(w) *Work day* means Monday through Friday excluding Federal holidays. Federal holidays include New Year's Day, Martin Luther King Jr.'s Birthday, Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, and Christmas Day.

(x) Any term defined in section 201 of the act shall have the same definition unless otherwise defined in this part.

§804.9 Public availability of reports.

(a) Any report, including any FDA record of a telephone report, submitted under this part is available for public disclosure in accordance with part 20 of this chapter.

(b) Before public disclosure of a report, FDA will delete from the report:

(1) Any information that constitutes trade secret or confidential commercial or financial information under §20.61 of this chapter; and

(2) Any personnel, medical, and similar information, including the serial numbers of implanted devices, which would constitute a clearly unwarranted invasion of personal privacy under §20.63 of this chapter; provided, that, except for the information under §20.61 of this chapter, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

Subpart B—Reports and Records

§ 804.25 Reports by distributors.

(a)(1) A distributor, other than an importer, shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that there is a probability that a device marketed by the distributor has caused or contributed to a death, serious illness, or serious injury.

(2) An importer shall submit to FDA a report, and a copy of such report to the manufacturer, containing the information required by § 804.28 on FDA form 3500A as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or medical or scientific literature, whether published or unpublished, that reasonably suggests that one of its marketed devices may have caused or contributed to a death or serious injury.

(b)(1) A distributor, other than an importer, shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the distributor receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the distributor has malfunctioned and such information reasonably suggests that there is a probability that the device or any other device marketed by the distributor would cause a death, serious illness, or serious injury, if the malfunction were to recur.

(2) An importer shall submit to the manufacturer a report containing information required by § 804.28 on FDA form 3500A, as soon as practicable, but not later than 10 working days after the importer receives or otherwise becomes aware of information from any source, including user facilities, individuals, or through the distributor's own research, testing, evaluation, servicing, or maintenance of one of its devices, that one of the devices marketed by the importer has malfunctioned and that such device or a similar device marketed by the importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

(c) Distributors as defined in part 897 of this chapter shall submit medical device reports concerning cigarettes and smokeless tobacco under this part only for adverse events related to contamination.

[58 FR 46519, Sept. 1, 1993, as amended at 61 FR 44615, Aug. 28, 1996]

§ 804.27 Where to submit a report.

(a) Any telephone report required under this part shall be provided to 301–427–7500.

(b) Any facsimile report required under this part shall be provided to 301–881–6670.

(c) Any written report or additional information required under this part shall be submitted to:

Food and Drug Administration,
Center for Devices and Radiological Health,
Distributor Report,
P.O. Box 3002,
Rockville, MD 20847–3002.

§ 804.28 Reporting form.

(a) Each distributor that submits a report on an MDR reportable event shall complete and submit the applicable portions of FDA form 3500A in so far as the information is known or should be known to the distributor, and submit it to FDA, and to the manufacturer as required by § 804.25.

(b) Each distributor shall submit the information requested on FDA form 3500A, including:

(1) Identification of the source of the report.

(i) Type of source that reported the event to thedistributor (e.g., lay user

owner; lay user lessee, hospital, nursing home, outpatient diagnostic facility, outpatient treatment facility, ambulatory surgical facility);

(ii) Distributor report number;

(iii) Name, address, and telephone number of the reporting distributor and the source that reported the event to the distributor; and

(iv) Name of the manufacturer of the device.

(2) Date information.

(i) The date of the occurrence of the event;

(ii) The date the source that reported the event to the distributor became aware of the event;

(iii) The date the event was reported to the manufacturer and/or FDA; and

(iv) The date of this report.

(3) The type of MDR reportable event, e.g., death, serious illness, serious injury, or malfunction, and whether an imminent hazard was involved;

(4) Patient information including age, sex, diagnosis, and medical status immediately prior to the event and after the event;

(5) Device information including brand and labeled name, generic name, model number or catalog number or other identifying numbers, serial number or lot number, purchase date, expected shelf life/expiration date (if applicable), whether the device was labeled for single use, and date of implant (if applicable);

(6) Maintenance/service information data including the last date of service performed on the device, where service was performed, whether service documentation is available, and whether service was in accordance with the service schedule;

(7) Whether the device is available for evaluation and, if not, the disposition of the device;

(8) Description of the event.

(i) Who was operating or using the device when the eventoccurred;

(ii) Whether the device was being used as labeled or as otherwise intended;

(iii) The location of the event;

(iv) Whether there was multi-patient involvement, and if so, how many patients were involved;

(v) A list of any other devices whose performance may have contributed to the event and their manufacturers, and the results of any analysis or evaluation with respect to such device (or a statement of why no analysis or evaluation was performed); and

(vi) A complete description of the event including, but not limited to, what happened, how the device was involved, the nature of the problem, patient followup/treatment required, and any environmental conditions that may have influenced the event.

(9) The results of any analysis of the device and the event, including:

(i) The method of evaluation or an explanation of why no evaluation was necessary or possible;

(ii) The results and conclusions of the evaluation;

(iii) The corrective actions taken; and

(iv) The degree of certainty concerning whether the device caused or contributed to the reported event;

(10) The name, title, address, telephone number, and signature of the person who prepared the report.

§804.30 Annual certification.

(a) All distributors required to report under this section shall submit an annual certification report to FDA, on FDA Form 3381, or electronic equivalent as approved under §803.14 of this chapter. The date for submission of certification coincides with the date for the firm's annual registration, as designated in §807.21 of this chapter. The certification period will be the 12-month period ending 1 month before the certification date, except that the first certification period shall cover at least a 6-month period from the effective date of this section, ending 1 month before the certification date.

(b) The distributor shall designate, as the certifying official, an individual with oversight responsibilities for, and knowledge of, the firm's MDR reporting system. A distributor may determine, based upon its organizational structure, that one individual cannot oversee or have complete knowledge of the operation of the reporting system at all organizational components or distribution sites owned by the firm. In this circumstance, the firm may designate more than one certifying official (one for each component or site),

each of whom will sign a certification statement pertaining to their respective identified organizational component(s) or site(s), provided that all organizational components and sites are covered under a certification statement.

(c) The report shall contain the following information:

(1) Name, address, and FDA registration number or FDA assigned identification number of the firm;

(2) Name, title, address, telephone number, signature, and date of signature of the person making the certification;

(3) Name, address, and FDA registration number or FDA assigned identification number for the distributor covered by the certification, and the number of reports submitted for devices distributed by the distributor;

(4) A statement certifying that:

(i) The individual certifying for the firm has read the MDR requirements under part 804;

(ii) The firm has established a system to implement MDR reporting;

(iii) Following the procedures of its MDR reporting system, the firm submitted the specified number of reports, or no reports, during the certification period; and

(iv) The certification is made to the best of the certifying official's knowledge and belief.

[62 FR 13306, Mar. 20, 1997]

§ 804.31 Additional requirements.

Requests for additional information. If FDA determines that the protection of the public health requires information in addition to that included in the medical device reports submitted to FDA under this part, the distributor shall, upon FDA's request, submit such additional information. Any request by FDA under this section shall state the reason or purpose for which the information is being requested, and specify a due date for the submission of such information.

§ 804.32 Supplemental information.

(a) Only one MDR is required under this part if the distributor becomes aware, from more than one source, of information concerning the same patient and the same event.

(b) An MDR that would otherwise be required under this section is not required by the distributor if:

(1) The distributor determines that the information received is erroneous in that a death, serious injury, serious illness, or the malfunction did not occur; or

(2) The distributor determines that the information received is erroneous in that the device that is the subject of the information was distributed by another distributor. A distributor shall forward to FDA any report that is erroneously sent to the distributor, with a cover letter explaining that the product in question is not distributed by that firm.

(c) A report or information submitted by a distributor under this part (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the party submitting the report or by FDA that the report or information constitutes an admission that the device, the establishment submitting the report, or employees thereof, caused or contributed to a death, serious injury, serious illness, or malfunction. A distributor need not admit, and may deny, that the report or information submitted under this part constitutes an admission that the device, the party submitting the report, or employees thereof, caused or contributed to a death or serious injury, serious illness, or malfunction.

§ 804.33 Alternative reporting requirements.

(a) Distributors may request exemptions from any or all of the reporting requirements in this part. These requests are required to be in writing and to include both the information necessary to identify the firm and device and an explanation why the request is justified.

(b) FDA may grant a distributor, in writing, an exemption from any or all of the reporting requirements in this part and may change the frequency of reporting to quarterly, semiannually, annually, or other appropriate time periods. In granting such exemptions, FDA may impose other reporting requirements to ensure the protection of public health and safety. FDA may also

authorize the use of alternative reporting media such as magnetic tape or disk, in lieu of FDA forms.

(c) FDA may revoke alternative reporting options, in writing, if FDA determines that protection of the public health justifies a return to the requirements as stated in this part.

§804.34 Written MDR procedures.

Device distributors shall maintain and implement written MDR procedures in the following areas:

(a) Training and education programs informing employees about obligations under this section, including how to identify and report MDR reportable events;

(b) Internal systems that provide for timely and effective identification, communication, and evaluation of events that may be subject to MDR requirements, a standardized review process/procedure for determining when an event meets the criteria for reporting under this part, and timely transmission of complete MDR's to FDA and/or manufacturers; and

(c) Documentation and recordkeeping requirements for:

(1) Information that may be the subject of an MDR;

(2) All MDR's and information submitted to FDA and manufacturers;

(3) Information that facilitates the submission of certification reports; and

(4) Systems that ensure access to information that facilitates timely followup and inspection by FDA.

§804.35 Files.

(a) A device distributor shall establish a device complaint file in accordance with §820.198 of this chapter and maintain a record of any information, including any written or oral communication, received by the distributor concerning all events that were considered for possible reporting under this part. Device incident records shall be prominently identified as such and shall be filed by device. The file shall also contain a copy of any MDR along with any additional information submitted to FDA under this part. A distributor shall maintain records that document the submission of copies of MDR's to manufacturers.

(b) A device distributor shall retain copies of the records required to be maintained under this section for a period of 2 years from the date that the report or additional information is submitted to FDA under §804.25, or for a period of time equivalent to the design and expected life of the device, whichever is greater, even if the distributor has ceased to distribute the device that is the subject of the report or the additional information.

(c) A device distributor shall maintain the device complaint files established under this section at the distributor's principal business establishment. A distributor that is also a manufacturer may maintain the file at the same location as the manufacturer maintains its complaint file under §§820.180 and 820.198 of this chapter. A device distributor shall permit any authorized FDA employee, during all reasonable times, to have access to, and to copy and verify, the records required by this part.

PART 805—CARDIAC PACEMAKER REGISTRY

Subpart A—General Provisions

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Subpart B—Submission of Information

805.10 Submission of information by physicians and providers.
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AUTHORITY: 42 U.S.C. 1395y(h), 1395y note.

SOURCE: 52 FR 27763, July 23, 1987, unless otherwise noted.

Subpart A—General Provisions

§805.1 Scope.

(a) This part provides for a nationwide cardiac pacemaker registry and requires any physician and any provider of services who requests or receives payment from Medicare for the implantation, removal, or replacement of permanent cardiac pacemakers and pacemaker leads to submit certain information to the registry. If the physician or the provider of services does not submit the information according